NDA 50-479/S-015

AUG 2 6 1999

King Pharmaceuticals, Inc.
Attention: Suzanne E. Smith
Manager, Regulatory Affairs
501 Fifth Street
Bristol, Tennessee

Dear Ms. Smith:

Please refer to your supplemental new drug application dated March 23, 1999, received March 24, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cortisporin (Neomycin and polymyxin B sulfate and hydrocortisone, USP) Otic Solution. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application provides for changes in the **Pediatric** and **Geriatric IJse** subsections of the **PRECAUTIONS** section of the package insert.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed draft labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling (text for the package insert, immediate container and carton labels) as indicated below.

Pediatric Use subsection:

> The safety and effectiveness of CORTISPORIN Otic Solution in otitis externa have been established in the pediatric age group 2 years to 16 years of age. There is inadequate data to establish safety and effectiveness in otitis externa for pediatric patients under 2 years of age.

Geriatric Use subsection:

> Clinical studies of CORTISPORIN Otic Solution did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-479/S-015." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up fonn, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 2l CFR 314.80 and 314.81.

If you have any questions, contact Ms. Frances V. LeSane, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research